

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1449V

UNPUBLISHED

KATHLEEN CARLOW,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 12, 2022

Special Processing Unit (SPU);
Entitlement to Compensation; Table
Injury; Decision Awarding Damages;
Pain and Suffering; Influenza (Flu)
Vaccine; Shoulder Injury Related to
Vaccine Administration (SIRVA)

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for Petitioner.

Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT AND DECISION AWARDING DAMAGES¹

On September 19, 2019, Kathleen Carlow filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”), alleging that she suffered a Shoulder Injury Related to Vaccine Administration (“SIRVA”) as a result of an influenza (“flu”) vaccine administered to her on September 20, 2016. Petition, ECF No. 1 at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

For the reasons described below, and after holding a brief hearing on entitlement and damages in this matter, I find that Petitioner is entitled compensation, and I award damages in the total amount of **\$83,410.29**, **consisting of \$77,500.00 for Petitioner’s**

¹ Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002, because it contains a reasoned explanation for my determination. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

actual pain and suffering, and \$5,910.29 for Petitioner's out-of-pocket medical expenses.

I. Relevant Procedural History

As noted above, this case was initiated in September 2019. On May 17, 2021, after attempting to resolve this case informally, Petitioner filed a status report stating that the parties had reached an impasse. (ECF No. 23). The parties requested that I issue a scheduling order setting deadlines for the parties to brief both the issues of entitlement and damages, and I did so. (ECF No. 24).

On July 22, 2021, Petitioner filed a Motion for Ruling on Record and Brief in support of Damages ("Motion"), arguing that she had established entitlement to compensation for her SIRVA injury, and requesting \$80,000.00 for her past/actual pain and suffering plus \$6,875.29 for her out-of-pocket medical expenses. (ECF No. 26). Petitioner specifically asserted that the evidence in the record preponderantly established that she received a vaccine in her left shoulder on September 20, 2016, that her shoulder injury began within 48 hours of receiving the vaccine, and that she was therefore entitled to compensation. *Id.*

Respondent filed a combined Rule 4(c) Report and Response to Petitioner's Motion on August 23, 2021 ("Response") recommending that entitlement to compensation be denied under the terms of the Vaccine Act. (ECF No. 26). Respondent argued that the Table criterion for SIRVA that required that pain and reduced range of motion be limited to the shoulder in which the intramuscular vaccine was administered had not been met in this case. *Id.* at 8. Respondent further asserted that Petitioner had not provided evidence sufficient to establish causation-in-fact under the relevant standard. *Id.* at 8-12. Petitioner filed his Reply on September 7, 2021. (ECF No. 28).

In May of this year, I proposed this case be set for an expedited "Motions Day" hearing on June 23, 2022³, at which time I would decide the disputed issues based on all evidence filed to date and any oral argument from counsel. (ECF No. 30). The parties agreed. (ECF No. 31). The Motions Day hearing took place on July 8, 2022. Minute Entry dated July 11, 2022. After the argument, I orally ruled on Petitioner's entitlement to compensation and made a damages determination as well. This Decision memorializes those findings/determinations.

³ The hearing was subsequently rescheduled and heard on July 8, 2022.

II. Factual Findings and Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁴ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

⁴ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

B. Factual Finding Regarding QAI Criteria for Table SIRVA

The only Table requirement for SIRVA that Respondent contests is the third criterion, i.e., whether Petitioner's pain and reduced range of motion were limited to her left shoulder. Response at 8. Based upon a review of the entire record, and for the reasons set forth below, I find that it likely was.

Respondent asserts that Petitioner's pain and reduced range of motion were not "limited to the shoulder in which the intramuscular vaccine was administered" because of multiple references in the record where Petitioner complained of pain radiating down her arm and into her hand the same day as she received her flu vaccine, as well as later

during her treatment course. See, e.g., Ex. 3 at 450; Ex. 4 at 1-2; Ex. 4 at 4-5, Ex. 9 at 2. Even though the record does establish these instances of non-shoulder pain complaints, I generally credit Petitioner's argument that her pain originated in her left shoulder and did not originate from another source. Reply at 2. And this is not a case where the bulk of Petitioner's complaints included an area broader than the shoulder region. On the contrary - the vast majority of records concentrate on Petitioner's complaints and treatment for *left shoulder pain*. See, e.g., Ex. 2 at 208 ("Pain is located anterior shoulder..."), Ex. 4 at 2 ("She has very restricted glenohumeral movement at the left shoulder."); Ex. 8 at 7 ("[P]atient reports in the last three weeks she has been experiencing increased discomfort throughout the left shoulder..."); Ex. 8 at 13 (showing left shoulder range of motion restrictions). Petitioner was diagnosed with adhesive capsulitis by at least three different providers, including Dr. Anthony Jesser, her orthopedic specialist. Ex. 4 at 59, 61-63, 66; Ex. 5 at 1-3. And to the extent that brachial neuritis was considered, subsequent testing ruled out that diagnosis. Ex. 4 at 18-19, 46-48.

At most, instances of complaints of pain in an area outside of the shoulder region are relevant to Petitioner's damages. But they do not defeat an otherwise-meritorious SIRVA claim – especially where there is ample and preponderant evidence of consistent, primary shoulder pain. Accordingly, this element of the claim has been met.

C. Other Requirements for Entitlement

As stated above, I find that Petitioner has satisfied all requirements for a Table SIRVA and is entitled to a presumption of causation. Even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), i.e., receipt of a covered vaccine, residual effects of injury lasting six months, etc. See *generally* § 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed. I therefore find that Petitioner is entitled to compensation in this case.

D. Damages

a. The Parties' Arguments

Citing seven⁵ prior damages determinations, Petitioner requests \$80,000.00 in actual pain and suffering. Motion at 2. She asserts that her course of treatment (including

⁵ Petitioner discusses the following cases in her Motion: *Binette v. Sec'y of Health & Human Servs.*, No. 16-0731V, 2019 WL 1552620 (Fed. Cl. Spec. Mstr. Mar. 20, 2019) (Special Master Dorsey); *Desai v. Sec'y of Health & Human Servs.*, No. 14-811v, 2021 WL 1292753 (Fed. Cl. Spec. Mstr. March 1, 2021) (Special Master Gowen), *Cooper v. Sec'y of Health & Human Servs.*, No. 16-1387; *Young v. Sec'y of HHS*, No. 15-1241V, 2019 U.S. Claims LEXIS 37 (Fed. Cl. Jan. 4, 2019), *Dhanoa v. Sec'y of Health & Human Servs.*, No. 15-1011V, 2018 WL 1221922 (Fed. Cl. Spec. Mstr. Feb. 1, 2018); *Kent v. Sec'y*

two EGM studies, an X-ray, MRI, steroid injection, and multiple rounds of physical therapy), is comparable to the aforementioned non-surgical SIRVA cases and warrants an award at that level. Motion at 1-2, 16-20. Specifically, Petitioner argues that she is entitled to an award similar to the award the petitioner received in *Binette*⁶ as “both Petitioners experienced moderate to severe shoulder injuries from vaccine administration that continued for several years.”⁷ Motion at 20. Petitioner also emphasizes that her medical records demonstrate that she endured pain and suffering for nearly three years, and that her symptoms continued to interfere with her ability to care for her young child and perform activities of daily living. Motion at 23-24; Ex. 10 at 1-2.

Respondent, by contrast, proposes an award of no more than \$65,000.00 for Petitioner’s pain and suffering. Response at 10, 12. He argues that “Petitioner’s medical records reflect that she sustained a comparatively minor injury and received some conservative treatment.” *Id.* at 10. Respondent cites to one case in particular – *Knauss v. Sec’y of Health & Human Servs.*, No. 16-1372V, 2018 WL 343296 (Fed. Cl. Spec. Mstr. Ma 23, 2018) – in which petitioner received \$60,000.00 for pain and suffering. But Ms. Carlow’s course of treatment was longer than Mr. Knauss’s course of treatment, justifying a slight increase on what was awarded in *Knauss*. Response at 11.

b. Legal Standards for Damages Awards

In another recent decision, I discussed at length the legal standard to be considered in determining damages and prior SIRVA compensation within SPU. I fully adopt and hereby incorporate my prior discussion in Sections II and III of *Berge v. Sec’y Health & Human Servs.*, No. 19-1474V, 2021 WL 4144999, at *1-3. (Fed. Cl. Spec. Mstr. Aug. 17, 2021).

In sum, compensation awarded pursuant to the Vaccine Act shall include “[f]or actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed \$250,000.” Section 15(a)(4). The petitioner bears the burden of proof with respect to each element of compensation requested. *Brewer v. Sec’y of Health & Human Servs.*, No. 93-0092V, 1996 WL 147722, at *22-23 (Fed. Cl. Spec. Mstr. Mar. 18, 1996). Factors to be considered when determining an award for pain and

of Health & Human Servs., No. 17-0073V, 2019 WL 5579493 at 2 (Fed. Cl. Aug. 7, 2019); *Goring v. Sec’y of Health & Hum. Servs.*, No. 16-1458V, 2019 WL 6049009 (Fed. Cl. Spec. Mstr. Aug. 23, 2019).

⁶ *Binette v. Sec’y of Health & Human Servs.*, No. 16-0731V, 2019 WL 1552620, *12 (Fed. Cl. Spec. Mstr. Mar. 20, 2019).

⁷ The petitioner in *Binette* was awarded \$130,000.00 in pain and suffering by former Chief Special Master Dorsey. 2019 WL 1552620, *12.

suffering include: 1) awareness of the injury; 2) severity of the injury; and 3) duration of the suffering.⁸

c. Appropriate Compensation for Pain and Suffering

In this case, awareness of the injury is not disputed. The record reflects that at all times Petitioner was a competent adult with no impairments that would impact her awareness of his injury. Therefore, I analyze principally the severity and duration of Petitioner's injury. When performing this analysis, I review the same record relied upon to determine entitlement, including the filed affidavits and medical records, written briefs, and argument at the Motions Day hearing. I have also considered prior awards for pain and suffering in both SPU and non-SPU SIRVA cases, and rely upon my experience adjudicating these cases.

The amount awarded for pain and suffering in this case takes special notice of the fact that Petitioner was pregnant at the time she received the vaccine, and therefore could not take advantage of the typical treatment of a shoulder injury such as prescription pain medications, steroids injections, and surgery. And then the subsequent burdens of caring for her newborn child while suffering from the SIRVA injury compounded her suffering.

Thus, in her affidavit, Ms. Carlow describes her frustration and the difficulty she encountered after her daughter was born. Pet. Ex. 10 at 1. She describes how difficult it was to nurse her newborn child and to pick her up from her crib, setting and putting her into her car seat, and breastfeeding. *Id.* After giving birth, Petitioner attended multiple rounds of physical therapy. Ex. 3 at 608, 630, 640, 651, 661; Ex. 4 at 23-24, 71; Ex. 8 at 1-6.11-13 She underwent an X-ray, MRI and several EMG studies of her left shoulder and was diagnosed with adhesive capsulitis. Ex. 4 at 1-2; Ex. 5 at 1-2. Nearly nine months after giving birth in November 2016, Ms. Carlow received a steroid injection in her left shoulder. Ex. 4 at 62. Her physician, Dr. Mercer, told her that recovery "will be slow..." Ex. 4 at 59. The most medical records dated August 16, 2019, noted "[p]ositive for arthralgias (shoulder)...", evidence of an ongoing shoulder injury nearly three years after vaccination. The pain and suffering award considers these specific facts and circumstances.

The parties' comparable case citations were reasonable, but not fully useful in helping me to calculate pain and suffering. I find that Petitioner's SIRVA more closely resembles the injury suffered by the petitioner in a case that was not cited by either party,

⁸ *I.D. v. Sec'y of Health & Human Servs.*, No. 04-1593V, 2013 WL 2448125, at *9 (Fed. Cl. Spec. Mstr. May 14, 2013) (quoting *McAllister v. Sec'y of Health & Human Servs.*, No 91-1037V, 1993 WL 777030, at *3 (Fed. Cl. Spec. Mstr. Mar. 26, 1993), *vacated and remanded on other grounds*, 70 F.3d 1240 (Fed. Cir. 1995)).

but also involves a petitioner that was pregnant at the time of vaccination. *Desrosiers v. Sec'y of Health & Human Servs.*, No. 16-0224V, 2017 WL 55078045, (Fed. Cl. Sept. 19, 2017). Because of her pregnancy, the *Desrosiers* petitioner similarly complained that she was unable to avail herself of traditional treatment options such as NSAIDS, steroid injections, and imaging because she was pregnant. *Desrosiers*, 2017 WL 55078045, at *5. And like Ms. Carlow, that petitioner also complained of difficulty in caring for her newborn son after birth due to the limitations with her shoulder. The *Desrosiers* petitioner was awarded \$85,000.00 for her pain and suffering.

Under such circumstances, and considering the arguments presented by both parties, a review of the cited cases, and based on the record as a whole, I find that \$77,500.00 in compensation for Ms. Carlow's actual pain and suffering is reasonable and appropriate in this case. Although Petitioner's request for \$80,000.00 is reasonable, and consistent with the "best" comparable in my view, I will discount this award slightly to account for the fact that Ms. Carlow complaints of pain were not wholly reflective of a SIRVA, but included non-compensable problems like pain radiating to her hand. I therefore award Petitioner \$77,500.00 for her actual pain and suffering.

d. Award for Past Unreimbursed Expenses

Ms. Carlow originally requested \$6,875.29 in past unreimbursable expenses. Motion at 24. Respondent, however, proposed only reimbursing Petitioner a total of \$5,910.29, disputing \$965.00 for a "specialty mattress for back pain" from Tuft & Needle, arguing that Petitioner had not established the reasonable necessity of the expense as required under Section 15 of the Vaccine Act. 42 U.S.C. § 300aa-15(a)(1)(B). During the hearing, however, Petitioner formally withdrew her request for reimbursement of that cost, leaving \$5,910.29 for her out-of-pocket medical expenses as a sum neither side disputes. Because I find the costs reflected in that sum to be reasonable, I award Ms. Carlow \$5,910.29 for past unreimbursable expenses.

E. Conclusion

In light of all of the above, the I award **Petitioner a lump sum payment of \$83,410.29, (representing \$77,500.00 for Petitioner's actual pain and suffering and \$5,910.29 for unreimbursable medical expenses) in the form of a check payable to Petitioner, Kathleen Carlow.** This amount represents compensation for all damages that would be available under Section 15(a) of the Vaccine Act. *Id.*

This amount represents compensation for all damages that would be available under Section 15(a). The Clerk of the Court is directed to enter judgment in accordance with this Decision.⁹

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

⁹ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.